Volume XXX, Number 17 Monday, December 4, 2023

»Virchow
Commentary on Managed Care Contracting
Why payers are skeptical about many LDTs
(see pages 12-14)

BREAKING NEWS!
OIG Advisory Opinion on Pathology Referral Arrangement
(see page 5-7)

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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

INSIDE THIS ISSUE

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Labs: Be Ready for Data to Dominate Diagnostics

BY NOW, IT SHOULD BE CLEAR TO CLINICAL LAB MANAGERS AND PATHOLOGISTS THAT THE GAME IN DIAGNOSTICS IS SHIFTING. Traditionally, lab managers considered a primary goal to be the reporting of accurate test results within the target turnaround times. Going forward, that will no longer be enough. Instead, labs will be rewarded for taking lab test data and using it to create knowledge and clinical intelligence that directly improves patient care. This is the Clinical Lab 2.0 ideal.

It may be serendipity that, within the next year or so, Millennials will make up 75% of the management and staff of clinical laboratories and anatomic pathology groups. This is a generation that grew up using digital data because the birth of personal computers coincided with the birth of the first Millennials.

The year 1981 saw the arrival of the Millennial Generation (birth years 1981 through 1996) and it was August 12, 1981, when the **IBM PC** debuted. Millennials—often called Gen Y—grew up as a host of electronic technologies were introduced and went mainstream, beginning in 1981 and continuing to the present. They include:

- Personal computers: Apple, PCs
- Fax machines
- Video games: Atari, Nintendo
- Dial-up modems
- Apple OS, Microsoft DOS
- Cell phones
- AOL, CompuServe, email
- Internet, World Wide Web
- Web browsers: Mosiac, AltaVista
- Blackberry phones
- Napster
- Social media sites: Facebook, LinkedIn
- iPod, Apple Music, Spotify, Pandora
- Smartphones: iPhone, Android
- Tablets, iPad
- Internet of Things, Alexa, Siri, Ring

Baby Boomer lab managers served during a time when an accurate lab test result reported within the target turnaround was a primary objective and measure of quality for a clinical laboratory. Soon, the primary objective of a laboratory—and a source of increased reimbursement—will be the lab's ability to deliver knowledge and clinical intelligence. The incoming generation of Millennial lab leaders will have the digital experience and skills needed to manage lab data and other data sources to keep their labs at the leading edge of clinical excellence in a financially-sustainable manner. TDR

Artificial Intelligence: Now a Priority for Labs

Swift and ongoing advances in AI technologies will be a challenge and an opportunity for labs

CEO SUMMARY: It's time to recognize the field of artificial Intelligence as the next major source of disruption. Not only will clinical laboratories, anatomic pathology groups, and diagnostics companies be disrupted by AI-powered technologies, but experts predict that almost every area of daily life may be transformed in some manner as artificial intelligence becomes more reliable while gaining more capabilities.

by Robert L. Michel

PREDICTING THE FUTURE CAN BE A RISKY BUSINESS. Yogi Berra, the baseball coach famed for his frequent malapropisms (more properly described as Yogiisms), had this to say about foretelling what is to come: "It is difficult to make predictions, especially about the future."

Yet, there are moments when current developments point to a clear picture of the future. Today, that is true of artificial intelligence (AI). The sheer volume of information about AI-related topics hitting the public daily is compelling evidence that a disruptive force is about to be unleashed upon society.

For example, each day brings a fresh wave of news stories about AI's potential to transform almost every aspect of life. Reinforcing these news reports are an incessant stream of press releases from companies new and old, big and small, about their plans and progress to bring an AI-powered solution to some aspect of business and medicine.

This is equally true of each edition of scientific publications and peer-reviewed medical journals where researchers describe their particular breakthrough with AI and its implications for medicine and the healthcare system.

Clinical lab administrators and pathologists will want to closely watch the advances of AI and its enabling technologies. This is particularly true in anatomic pathology, where the leading edge of AI-powered solutions is directed toward digital pathology and algorithms designed to interpret whole slide images (WSIs) or guide pathologists to specific features in a WSI.

THE DARK REPORT expects that, in the coming 12 to 36 months, almost every

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product or service presented to a laboratory will include an artificial intelligence-powered solution. For that reason, THE DARK REPORT suggests that it is timely for lab managers at all levels of the organization to begin to learn about the field of artificial intelligence.

One important insight about AI is that there are multiple, distinct technologies being incorporated into any company's AI solution. Most common today are machine learning (ML), deep learning (DL), natural language processing (NLP), and neural networks (NNs), to name a few. The sidebar at right has a larger list of terms now associated with AI.

Stated differently, an AI solution presented to a lab today may be built upon any of 31 flavors of technology, to paraphrase the **Baskin Robbins** tag line. In coming years, when a vendor presents a product or service to a lab that has an AI component, the lab buyer will want to understand what specific technologies are under the hood and powering that AI solution.

Today's AI Comes with Flaws

Moreover, many of today's AI offerings have their own flaws. Some journalists, when using things like **OpenAI's** ChatGPT to compose stories and reports, have written about how the particular AI solution they were using had made up facts. In one case, the reporter said the AI product he used to create a study paper actually inserted footnotes that quoted books that did not exist. The AI had made up the references it footnoted!

Another example of the speed of change and adoption is the news that in September, **Boston Children's Hospital** hired Dinesh Rai, MD, to be its first "AI Prompt Engineer." This is believed to be the first hospital to create this position. *MedPage* wrote that "prompt engineering is the practice of creating commands for AI programs with the goal of generating a desired response or output." TDR

Artificial Intelligence Has a New Vocabulary

GIVEN THE RAPID ADVANCES IN ARTIFICIAL INTELLIGENCE (AI) AND RELATED TECHNOLOGIES, lab managers will need to learn the vocabulary associated with AI. **Salesforce** posted a blog, "AI from A to Z: The Generative AI Glossary for Business Leaders" that presents a growing list of terms, listed below.

Generative AI Terms by Topic

AI CORE TERMS

- Artificial intelligence (AI)
- Artificial neural network
- Augmented intelligence
- CRM (customer relationship management) with AI
- Deep learning
- Generative AI
- Generator
- Generative Pre-trained Transformer
- Machine learning (ML)
- Natural Language Processing (NLP)
- Parameters
- Transformer

AI TRAINING & LEARNING

- Generator
- Grounding
- Hallucination
- Large Language Model (LLM)
- Model
- Prompt engineering
- Reinforcement learning
- Sentiment analysis
- Supervised learning
- Unsupervised learning
- Validation
- Zone of Proximal Development (ZPD)

AI ETHICS

- Anthropomorphism
- Ethical AI Maturity Model
- Explainable AI (XAI)
- Human in the Loop (HITL)
- Machine learning bias
- Prompt defense

Regulatory Update

Anatomic Pathology Referrals Topic of OIG Advisory Opinion 23-06

At question was an arrangement for TC/PC services involving patients covered by commercial health plans

THANKS TO A RECENTLY-RELEASED ADVISORY OPINION issued this fall by the **Office of the Inspector General (OIG) Department of Health and Human Services,** there is a new compliance twist involving billing for the technical component (TC) for anatomic pathology procedures.

Advisory Opinion No. 23-06 was released on Sept. 25, 2023. In the opinion, the OIG wrote that certain payment arrangements involving the purchase of the technical component of anatomic pathology services could violate the federal Anti-Kickback Statute (AKS) of the Social Security Act, even if the purchased services are limited to patients who are commercially insured.

"OIG has a longstanding concern about arrangements under which parties carve out referrals of federal healthcare program beneficiaries or federal healthcare program business from otherwise questionable financial arrangements," the opinion states.

Request for Opinion

Advisory opinion No. 23-06 came in response to a query made on behalf of an anatomic pathology lab, identified only as "Requestor."

The Requestor stated that it had been approached by other laboratories proposing business arrangements under which the Requestor would:

- Purchase the technical component (TC) of anatomic pathology services from the other lab, defined in the opinion as "physical preparation of the specimen, which results in the production of a glass slide for review by a pathologist."
- Perform the professional component (PC) of the services, meaning "the analysis of the slide by the pathologist," and then bill commercial insurers as in-network provider for both components.
- Pay the referring lab "a fair market value, per-specimen fee for performing the technical component of the referred tests."

The alleged entities that approached the Requestor included physician labs—those at least partially owned by physicians, or those that employ physicians, according to the opinion—and non-physician labs that do not have physician owners or employees. In both cases, the purchased services would exclude patients covered by federal healthcare programs.

Why would the labs propose such a deal? "According to Requestor, although some Physician Laboratories and Non-Physician Laboratories may have the capability to perform both the professional and technical components themselves, they wish to enter into the Proposed Arrangement because they are unable to bill certain commercial payers for anatomic pathology services, or they are not in-network with certain commercial payers," the opinion states.

The OIG didn't state why the labs referenced in the opinion are unable to bill some payers. But two healthcare attorneys

familiar with lab industry practices each noted a variety of other possible reasons, aside from being out of network. Both asked not to be identified.

"Number one, most commercial payers don't allow split billing," one attorney said. "They don't allow laboratories to bill just for the technical component, or just for the professional component. They require a global bill.

"So, why doesn't the lab furnishing the technical component perform the professional component itself and bill globally?" asked the attorney. "The professional component could require a specialist pathologist that the physician labs or non-physician labs may not have on staff, or they may simply not have a pathologist on staff. So they must send to a lab that does."

An Unfavorable Opinion

Based on the information provided by the Requestor, the OIG concluded that the Proposed Arrangement "would generate prohibited remuneration under the federal Anti-Kickback Statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions."

At the crux of the opinion is the Requestor's assertion that "performing both components in-house is generally more efficient and cost-effective than paying a third-party lab," the opinion stated.

"The Requestor's assertion that the proposed arrangement was not commerically reasonable has caused the legal community to question the legitimacy of the request," both attorneys said.

And while the proposed arrangement was limited to commercially insured patients, the Requestor asserted that the physician labs or non-physician labs would be in a position to refer future work involving patients covered by federal healthcare programs.

As a result, the OIG concluded "it is difficult to discern any commercially reasonable business purpose for Requestor to enter into the Proposed Arrangement—forgoing the opportunity to bill and retain payment for both components of the anatomic pathology services, in an arrangement that is both less efficient and more costly—other than the possibility that such payment may induce referrals of patients, including federal healthcare program beneficiaries."

Seeking a Safe Harbor

"In short, this advisory opinion says, 'We think the proposed arrangement would not be compliant because it doesn't meet all of the criteria under the Anti-Kickback Statute safe harbor for personal services arrangements,'" the second healthcare attorney noted. "And it identifies the specific criteria that are not met.

"Safe harbors," the attorney explained, "define specific payment arrangements that would otherwise violate the statute but are regarded as being proper. Some are spelled out in the statute, whereas others are established administratively in regulation."

One safe harbor in the Anti-Kickback Statute is commonly known as PSMC, for "Personal Services and Management Contracts," the attorney said.

"Like many other safe harbors, it has a test of specific criteria that must be satisfied," the second attorney noted. "There must be a signed contract. It must be for a one-year term. With recent amendments in 2021, the compensation formula must be set forth in advance. It's pretty easy to meet those criteria.

Commercially Reasonable?

"But then we get to the critical piece of the advisory opinion, which is more subjective in nature, but requires objective support," continued the attorney.

"Is the purchase price or compensation set at fair market value? Is it negotiated at arm's length? If a lab went out to any other party that wasn't in a position to make a referral, would that lab pay the same amount?" the attorney stated.

"It is very common in pathology services that the technical component of pathology services is purchased from another laboratory and then billed globally," the attorney observed.

But in this advisory opinion, the OIG "is primarily homing in on one criterion that is very broad," the attorney said. "Are the parties entering into a commercially reasonable business arrangement? Is it for a legitimate business purpose? Or are they doing it for the referral of federal healthcare program business?"

The OIG is "not saying that the arrangements are not permissible," the attorney stressed. "But based on the facts that were presented, the OIG did not believe that the Requestor had demonstrated why there would be a commercially reasonable business purpose for this arrangement, except for generating future referrals."

In-house Testing

The opinion itself stated that "we have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement."

The first attorney contended that there are many scenarios where it could make sense, from a business standpoint, to purchase the technical component from another lab.

"The Requestor said that performing both components in-house is more efficient and cost effective," observed the first attorney. "But though it may be more cost effective to purchase it, it's not just the cost of the technical component. It's courier services and storing the glass slides and samples, maybe for 10 years in some instances. There are additional costs that can factor into whether it's commercially reasonable.

"Do they have the staff to be able to do that?" the first attorney continued. "Someone has to have the skills to gross the sample, stain the sample, prepare it, all of those things. Some of the stains are fairly common and straightforward, but some are very specialized.

"There are many factors that are relevant to why this could be commercially reasonable outside of 'We're entering into this arrangement in order to secure or induce a referral to our lab,'" the first attorney noted.

Impact on Pathology Labs

"When the OIG releases an advisory opinion—while technically it can only be relied upon by the Requester—it provides guidance to the market about what may or may not be, in the OIG's opinion, a violation of the Anti-Kickback Statute," the attorney said.

"With this advisory opinion out there, labs should understand that this type of payment arrangement could be an issue that the OIG may further investigate," the second attorney added. "This is because the OIG oftentimes issues special fraud alerts or advisory opinions right before they actually start to take enforcement action.

"What I would say to any client is, 'If you're entering into a payment arrangement—especially with a physician lab that is making referrals to your lab—you have to be concerned about complying with the Anti-Kickback Statute, Stark, and EKRA,'" the attorney noted.

Payment Arrangements

The latter two laws refer to the federal Stark Law and Eliminating Kickbacks in Recovery Act, which also may restrict payment arrangements involving physician referrals.

"With that being said, we know there's a safe harbor," the second attorney stated. "When a laboratory enters into any of these arrangements, it is essential to ensure that it meets all the criteria under the safe harbor." TDR

CLIA Lab Directors Must Watch Delegated Duties

Most frequent citations for lab director roles and responsibilities point to challenges with the job

Denise Driscoll, MS, MT(ASCP)

CEO SUMMARY: *Laboratory accreditors warn that underestimating or overlooking the duties of a lab director can lead to citations during CLIA inspections. Presented here are the most-frequently cited violations of the CLIA lab director's duties and responsibilities as documented during lab inspections conducted in 2022 by CAP, COLA, TJC, and A2LA.*

Kathy Nucifora, MPH, MT(ASCP)

Editor's note: This is the final installment in an occasional series of inspection readiness briefings that focus on how to avoid the most common citations seen during inspections under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

DURING INSPECTIONS BY CLIA DEEMING ORGANIZATIONS, laboratory directors are flagged for problems with laboratory director roles and responsibilities, such as maintaining overall lab performance and reviewing documentation.

Guidance about this topic was shared at the *2023 Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management* and in follow-up interviews with THE DARK REPORT. A panel of CLIA accreditors previously discussed their respective lists of the top 10 deficiencies noted during each of their organizations' CLIA (Clinical Laboratory Improvement Amendments) inspections in the prior year. *(See TDR, "CLIA Lab Accreditors Reveal Most Frequent Deficiencies," May 30, 2023.)*

How laboratory directors meet their responsibilities is assessed during inspections by the four major CLIA accrediting groups:

- **The Joint Commission**.
- The **American Association for Laboratory Accreditation** (A2LA).
- **COLA**.
- The **College of American Pathologists** (CAP).

Lab Director Regulations

CLIA falls under Section 493 of the Code of Federal Regulations. Subpart M addresses general laboratory director responsibilities as follows:

- The laboratory director is responsible for the operation of the laboratory, including employment of personnel who are competent to perform tests and report test results accurately.
- The lab director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities. If delegated, the lab director must ensure these duties are performed properly.

- Other provisions that fall to lab directors concern testing methodologies and proficiency testing (PT) procedures.

COLA: Monitor Delegation

COLA's assessors note that there are limitations to how much lab directors can delegate. It is risky for directors to pass off too many duties to technical supervisors and technical consultants.

"A good technical leadership team that works closely with the laboratory director is critical," said Kathy Nucifora, MPH, MT(ASCP), Chief Operating Officer at COLA. "Laboratory directors are responsible for ensuring that their CLIA-defined responsibilities are being met, even if those responsibilities have been delegated. So, their responsibility doesn't stop with delegating."

Laboratory directors must gauge how often they sit down with the technical consultants and supervisors. "It's important that directors meet with the technical leadership team on a regular basis," Nucifora explained. "A laboratory director has to stay engaged with the laboratory to ensure that the delegated responsibilities are being met. This is not always accomplished solely by adding meetings to the calendar, although frequency is important.

"A good laboratory director will review progress on delegated responsibilities during these important meetings," she added. "Directors should delegate responsibilities where CLIA allows, but they shouldn't abdicate responsibilities."

A2LA: Lab Director Self-Checks

Laboratory directors can better stay on top of duties required by CLIA rules by making time for self-check-ins.

"A2LA has seen successful laboratory directors perform monthly or biweekly check-ins with themselves," noted Carlyn Mathews, Clinical Program Manager at A2LA. "They go through these self-checks asking themselves, 'Am I hitting these responsibilities? Are tasks that I delegate getting done with the proper amount of oversight?' These self-checks can help because a lot of lab directors are spread very thin right now.

"We've seen laboratory directors entering items in a calendar so that they know that on this specific day, for example, they're going to check on proficiency testing, and on another day, they will check on a different activity," she added. "That approach can be helpful in keeping accountability to meet their duties as defined by CLIA."

Carlyn Mathews

"Laboratory directors must make sure that their direct reports understand what they've been delegated and the duties for which they are responsible."

Another type of check-in that is effective occurs between lab directors and those to whom the directors delegate duties. "Taking 15 minutes each month to have a personal conversation with the people who have been delegated duties helps both sides work through any issues," Mathews noted. "Laboratory directors must make sure that their direct reports understand their delegated duties for which they are responsible."

CLIA lab directors are also wise to ask bench staff about what problems they are experiencing with processes. "Frontline laboratory personnel are doing the work in day-to-day operations and the testing of patient samples, so they see the problems," Mathews said. "It's up to laboratory directors to make those connections with frontline staff, especially if there's a divide between what's in a procedure manual and what actually happens in the lab.

"The lab might have a procedure to make a process more efficient, for example, so it's up to the laboratory director to offer training to staff on this efficiency," she continued. "And by promoting this

efficiency, the work may be of higher quality and frontline workers won't be as tired. Directors can make their personnel happier."

TJC: More Training

The Joint Commission's prime deficiency for CLIA laboratory directors sits within its leadership standards. These standards can be a difficult predicament for labs with new directors.

"Often, CLIA laboratory directors are not as knowledgeable as they need to be about the CLIA regs and the standards specific to the accrediting agency surveying them," said Amy Null, MBA, MT (ASCP)SBB, Associate Director for the Standards Interpretation Group, Laboratory Accreditation at The Joint Commission.

Amy Null, MBA, MT(ASCP)

➤"Often, lab directors are not as knowledgeable as they need to be about the CLIA regs and the standards specific to the accrediting agency surveying them."

"This situation may exist because they have no formal training or even orientation to the role of CLIA laboratory director as defined by their accrediting organization," she noted.

Many in the medical laboratory industry can relate to those times when a lab director retires or leaves the post. To quickly fill the position, a bench tech or pathologist is offered the role.

"One day this person is doing their old job, and then the next day they're a lab director under the lab's CLIA license," Null observed. "They walk into that new role, and they're asked to perform all the functions of a laboratory director. In such situations, these individuals may be assuming the position without knowledge and training on the full range of their responsibilities under CLIA.

"Suddenly this new person is reviewing documentation, signing policies and procedures, and making administrative decisions," she continued. "It's a huge responsibility. Ultimately, CLIA says that everything that happens in that laboratory is the lab director's responsibility. In these situations, it's important to ensure this new lab director gets a formal orientation and is trained to the role of the lab director."

Null suggested that forward-thinking labs develop orientation and training for people who get abruptly dropped into the job of a CLIA laboratory director.

"That's a hard situation, however. Laboratories are spread too thin," Null observed. "Labs don't have the time to train new directors. The lab needs that position filled. They're not allowed to have a CLIA number without a lab director.

"So, if a current lab director leaves, the lab must immediately fill that opening," she said. "As a lab community, we really should be helping labs to solve this problem."

CAP: Mentor Younger Staff

CAP's main citation regarding laboratory directors points to a requirement for a PT attestation to be signed by a director or designee.

That is a narrow provision, but in the larger picture, the hubbub of every day life in a clinical laboratory can contribute to directors and frontline staff overlooking important details, said Denise Driscoll, MS, MT(ASCP)SBB, Senior Director for Laboratory Accreditation and Regulatory Affairs at CAP.

"A lot of CAP's requirements have been in place for a long time," Driscoll noted. "But many labs are regularly turning over staff and bringing in new employees. Maybe those new workers haven't come from a traditional clinical laboratory scientist training program, so they don't automatically think to a certain level of detail about lab work.

Standards Cited for Duties of CLIA Laboratory Directors

During 2022, the following four CLIA accreditors frequently cited these standards for CLIA laboratory directors:

A2LA

- 493.1445 (b)—If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

The Joint Commission

- LD.04.05.07 (Leadership), Element of Performance 4—The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining laboratory performance.

COLA

- LDR 4 (Laboratory Director Responsibilities)—Laboratory director fulfills the proficiency testing responsibilities of the position.
- LDR 5—Laboratory director fulfills the quality control and quality assessment responsibilities of the position.
- PT 15 (Proficiency Testing)—PT records include attestations signed by the laboratory director and testing personnel.
- PT 16—Laboratory director reviews PT results with supervisory staff and testing personnel.

CAP

- COM.01400 (All Common Checklist, PT Attestation Statement)—The proficiency testing/external quality assessment attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.

"Laboratory directors need to mentor and teach these new frontline employees," she added. "Directors and other supervisors need to have the time to think about their responsibilities. Performing those duties can be a challenge when they are running patient tests."

CLIA Inspection Themes

One useful insight in this series about frequently cited citations by the four major CLIA accrediting organizations: many deficiencies noted during CLIA inspections are failures to follow long-established requirements in labs. The reasons for these slipups are myriad, but several themes recur:

- At times, clinical laboratory leaders don't carefully assess CLIA-related problems in the lab or document the steps an organization takes to correct these problems.
- CLIA laboratory directors may not monitor their delegation of duties as closely as specified by requirements.
- Labs sometimes fail to establish reporting systems and metrics to measure how well laboratory directors, technical consultants, technical supervisors, and frontline staff meet their responsibilities under the requirements of CLIA.

The information presented here is unique in that all four CLIA accrediting organizations are sharing their respective experiences that pertain to assessing the performance of a lab's CLIA laboratory director.

All four organizations recommend the need for CLIA laboratory directors to carve out time to regularly monitor their own job performance. The objective is to allow them to make adjustments in their schedule should they determine there are recurring gaps in delegated duties. TDR

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Virchow
Medicine ➤ Money ➤ Managed Care

This column is named after the famous German pathologist, Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Payers Are Right to Be Wary of Claims for Some LDTs' Value

EDITOR'S NOTE: Our column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

THERE'S PLENTY OF NOISE RIGHT NOW in the market about laboratory-developed tests (LDT). That comes as no surprise. LDTs—which are often genetic tests—are like the Wild West in the clinical laboratory industry. News stories document how some doctors are making decisions based on faulty results from inaccurate or even bogus LDTs.

By now, you've probably heard that the federal **Food and Drug Administration** (FDA) has issued a proposed rule that would move oversight of LDTs under the agency. The public comment period is scheduled to close on Dec. 4. *(See TDR, "FDA Issues Proposed Rule to Further Regulate LDTs," Oct. 2, 2023.)*

As someone in managed care, I understand that many people in healthcare get nervous any time the FDA starts sticking its nose into some area of medical technology. On the "positive side" of the LDT spectrum, it is a fact that not all LDTs are problematic. Many LDTs showcase innovative thinking, clearly benefit patients, and that's how new testing becomes relevant.

However, on the "negative side" of the LDT spectrum, proponents of more LDT regulation can point to visible problems. One example in recent years is the blatant corruption in the lab test market involving numerous fraudulent COVID-19 lab companies that pushed out questionable LDTs to consumers during the pandemic.

➤ NIPTs Are Not the Same

When someone mentions LDTs to me, the first thing I think of is NIPT—Non-Invasive Prenatal Testing. These genetic tests present health plans with a host of challenges.

All labs that offer NIPT have different versions of it. Various tests can have four components, six components, 10 components, 12 components—but often a physician probably only needs three of the components to properly screen a fetus, given family history and other relevant factors.

One LDT problem for payers is variability when one lab's NIPT panel is compared with another lab's NIPT panel. Performed as LDTs, then coded and submitted for reimbursement, many NIPT claims don't help the health plan recognize what clinical benefits these different NIPT panels do for the patient.

This problem exists because any lab can offer NIPT as an LDT, give it a proprietary name, and attach a Current Procedural Terminology (CPT) code to it. Or they could even obtain a PLA code.

During prior-authorization, or when the NIPT test claim is presented, payers really don't know what's in that test. However, that is only one part of the problem.

Another issue with NIPT tests as LDTs is the recognition by payers that, unfortunately, some parents make decisions for their unborn child based on LDT components and genetic test results that might have been inaccurate, inappropriate to the physician's concerns, or even bogus.

Another long-standing issue with genetic tests is the frequent use of CPT code 81479, which is for unlisted molecular pathology. This CPT code is a catch-all for novel molecular assays.

One attempt to address this problem came in 2016. That's when the **Centers for Medicare and Medicaid Services** (CMS) came up with Proprietary Laboratory Analyses (PLA) codes in an attempt to straighten out this mess. PLA codes—which are numbered 0001U through 0241U—allow labs and manufacturers to specifically identify their tests.

About that time, CMS also created a crosswalk to the CPT and PLA codes that, in theory, shows an existing test code that is comparable to a new LDT. Crosswalk calculations are made for a new or substantially revised LDT that is comparable to an existing test. The existing test code is used to determine payment.

There are also gap fills. Gap-fill calculations are made when no comparable existing test is identified in a crosswalk.

Not That Straightforward

All of these new codes, crosswalks, and gap fills sounded good, but they're not that straightforward. Thus, claims for LDTs with a PLA code did not truly give a payer more insight into what the test was intended to do than when a genetic testing company was stacking assays.

Think of it this way: When you walk into a store, pick up a bottle of wine, and put down your $20, you know what you paid for. Genetic testing companies perform these LDTs and it doesn't matter whether they use a CPT code, an unlisted code, or a PLA code. When the claim arrives, health plans still don't know precisely what they are paying for on behalf of their beneficiaries.

This confusion served as the basis for the introduction of Z-codes, which has been written about in past Virchow columns. Remember, at some point in 2024, it's expected that **UnitedHealthcare**—and perhaps other payers—will require Z-codes for molecular diagnostic test claims under commercial plans. *(See TDR, "Virchow: With Z-Codes, Will Other Payers Follow UnitedHealthcare's Lead?" July 31, 2023.)*

Z-codes Identify Genetic Tests

Z-codes are five-digit, alpha-numeric identifiers that are assigned to molecular assays that are performed by a particular lab—including LDTs. The codes identify molecular test components, which can vary greatly as I noted earlier.

Z-codes are listed under the DEX Diagnostic Exchange. DEX is a molecular test identification system established by **Palmetto GBA**, the Medicare Administrative Contractor. In theory, once a lab applies for a Z-code for an LDT, it should be clear what the components of that test are and whether a payer will reimburse for a related claim. Palmetto completes a Technical Assessment prior to issuing a Z-code.

I know everybody has this concept that health plans don't want to pay labs for claims. But that's not true. They do want to pay for medically necessary testing that benefits our patients.

However, I think things have gotten so out of control with LDTs that we—as the collective health insurance industry—are being inundated with claims for a wide range of LDTs where there is little supporting documentation for analytical validation (accurate results) and clinical validation (showing that the results

improve diagnosis and treatment of patients).

If the goal for a payer, the physician, and labs is to provide the right test to the right patient at the right time, many LDTs fall short of that goal because these assays lack documentation showing accuracy and clinical validity.

Reason to Be Suspicious

I'm going to be blunt: For all the reasons listed above, most of those on the payer side are suspicious of every genetic testing lab when it comes to LDTs. This is true whether it's a genetic testing lab, hospital lab, or academic medical center lab.

I know of a very well-known laboratory that acted worse with LDTs than some of those shady COVID pop-up labs. The economics are powerful. It is easy for the investors and bean counters in genetic testing companies to ask, "Why can't you stack the assays? Then, we could get $12,000 for this test instead of $8,000."

All of this is to explain why friction exists between labs and health plans when payers need to determine the answer to the basic question: should a claim for an LDT test be paid if the health plan doesn't have any details about the LDT.

For example, if a genetic testing company submits an LDT claim using unlisted code 81479, it will probably end up in what's called "pending pay hell." This means their payment for that claim is pending based on a variety of factors that should have been met ahead of time.

Trust Between Payer, Lab

If a lab has a contract with a payer, and that contract states that a fictional lollypop test will be filed under 81479 and get reimbursed at $400, then—per the payer/lab contract—that claim will go through if everything lines up. The test is probably an LDT, but the payer trusts the lab with which it contracted.

When it comes to LDTs, payers want transparency and documentation supporting the clinical validity of the test. To quote a published paper, that includes an LDT's "sensitivity (ability to identify individuals with the condition correctly), specificity (ability to identify individuals without the condition correctly), positive predictive value (the probability that a positive test result indicates the presence of the condition), and negative predictive value (the probability that a negative test result indicates the absence of the condition)." TDR

Upcoming Comments on FDA Proposal

GIVEN THE FOOD AND DRUG ADMINISTRATION'S (FDA) notice of proposed rulemaking to tighten up oversight of laboratory-developed tests (LDTs), it will be interesting to see what public comments come in before the comment period closes on Dec. 4.

Personally, I can't wait to see what everybody's saying—genetic testing labs, academic medical centers, health systems, the national lab companies, and *in vitro* diagnostics manufacturers. They all have a stake in the LDT market.

It's reported that more than 1,900 public comments had been submitted to the FDA by mid-November. This shows the high interest in this proposed FDA regulation of LDTs.

When I asked a handful of people what they thought of the FDA proposal, they shuddered as if somebody walked over their grave. Government intervention in the marketplace is generally not popular. But when one steps back and looks at the preponderance of genetic tests offered as LDTs, some type of action is warranted.

And the payers? Who knows if they'll comment. Payers may sit back and wait till the comment period ends and then see what people said about the proposed LDT rule to better gauge clinical laboratory industry feelings.

IVD Update

Most IVD Firms Increase Q3 2023 Base Business Revenue

Manufacturers adding assays, advancing technology, increasing footprints in clinical labs

Most in vitro diagnostics (IVD) companies reported increases in base business during the third quarter (Q3) 2023. The numbers, in the single digits, softened the blow from the continuing drop-off in COVID-19 test sales.

Manufacturers of tests and laboratory instruments are launching new diagnostics solutions, making greater use of technology, and eyeing possible acquisitions as they aim to step up traction of their brands in clinical laboratories.

Here is a summary of the most recent financial reports from some of the world's largest IVD companies.

HOLOGIC: Reports Base Revenue Increased in Q4 by 17.5%

Hologic, based in Marlborough, Massachusetts, reported financial results for Q4 2023 and full fiscal year 2023, as compared to Q4 2022 and 2022:

- Base revenue in Q4 grew 17.5%.
- Q4 diagnostics revenue fell 20.1% to $416.4 million from $520.9 million.
- Q4 molecular diagnostics revenue fell 27.1% to $291.9 million from $400.2 million.
- Full year revenue fell 16.6% to $4.0 billion from $4.8 billion.
- Q4 revenue was down 0.8% to $945.3 million from $953.2 million.

CEO Steve MacMillan told analysts during an earnings call that Hologic has installed 3,620 Panther instruments worldwide and that future growth may come through expanded menus.

"Now it's really ramping up the menu with our existing customers. And an increased focus on expanding the (Panther) Fusion (respiratory assays). So, I think the magic for us is now that we have so many Panthers installed, we're increasingly going back and getting the Fusion sidecar put on, which opens up the PCR assays."

THERMO FISHER: Advances Solutions for Research, Plans to Acquire Olink for $3.1 Billion

Thermo Fisher Scientific in Waltham, Massachusetts, shared these Q3 results versus Q2 2022:

- Revenue declined 1% to $10.5 billion from $10.6 billion.
- Laboratory products and biopharma services segment revenue increased 3.6% to $5.7 billion from $5.5 billion.
- Life sciences solution segment revenue fell 17.2% to $2.4 billion from $2.9 billion.
- Analytical instruments segment revenue was up 13% to $1.7 billion from $1.6 billion.
- Specialty diagnostics segment revenue was flat at $1 billion.

In Europe, Thermo Fisher launched EXENT, a protein diagnostics solution

aimed at diagnosis and monitoring of patients with blood protein abnormalities related to multiple myeloma and other disorders.

During an earnings call, CEO Marc Casper commented on the recently announced planned acquisition of **Olink**, a Sweden-based company aimed at human protein biomarker discovery. The $3.1 billion deal, he said, "underscores the profound impact that proteomics is having as our customers continue to advance life science research and precision medicine."

He also noted these new Thermo Fisher offerings: the Orbitrap Astral Mass Spectrometer aimed at protein discovery research, and the Hydro Bio Plasma-FIB which uses electron microscopy to analyze tissues to proteins.

"Science continues to advance at a rapid pace, and our tools are used by scientists for the most important work that they do," Casper said.

QuidelOrtho

QUIDELORTHO: Posts Uptick in Sales to Labs, Reduces Instrument Backlog

QuidelOrtho in San Diego reported Q3 data as compared to Q3 2022:

- Revenue of $744 million was down 5.1% from $783.8 million.
- Labs revenue of $341.4 million was up 2.1% from $334.8 million.
- Point-of-care revenue was down 13.8% to $233.1 million from $270.5 million.
- Molecular diagnostics revenue plummeted 63.6% to $5.6 million from $15.4 million.

During an earnings call, CEO Douglas Bryant said the labs' instrument backlog is "returning to normalized levels," and that the company is "primed to meet customer demand moving forward."

He added COVID-19 "has clearly moved into an endemic state. However, we expect it to remain a persistent respiratory pathogen for many years to come."

Abbott
A Promise for Life

ABBOTT LABORATORIES: Diagnostics Base Business Revenue Up 8.8% during Q3

Abbott Laboratories in Abbott Park, Illinois, shared these Q3 financial results as compared to Q3 2022:

- Total sales decreased 2.6% to $10.1 billion.
- Diagnostics sales fell 33.3% to $2.4 billion from $3.6 billion.
- Diagnostics base business grew 8.8%.
- COVID-19 testing revenue plunged to $305 million compared to $1.6 billion.
- Core laboratory sales were up 8.3% to $1.3 billion from $1.2 billion.
- Molecular sales plummeted 27.3% to $133 million from $183 million.

During an earnings call, CEO Robert Ford addressed the growth of diagnostics base business. "Growth was driven by a continued increase in global demand for routine diagnostics testing and a strong recovery of our blood transfusion testing business, following a period of lower plasma donations that occurred during the COVID-19 pandemic," he said.

BIOMÉRIEUX

BIOMÉRIEUX: Reports Q3 Sales, Announces New Respiratory Panel

bioMérieux, in Marcy-l'Étoile, France, shared financial results during Q3 2023 as compared to Q3 2022, as follows:

- Sales were down 0.4% to €898.4 million (US$982.5 million) from €902 million (US$986.5 million).
- Microbiology sales of €321.6 million (US$351.8 million) were up 3.2% from €311.8 million (US$341.0 million).

- Immunoassays sales were down 7% to €94.2 million (US$103.0 million) from €101.4 million (US$110.9 million).
- Molecular biology sales fell 1.7% to €327.9 million (US$358.6 million) from €333.5 million (US$364.7 million).

During the quarter, the company said it submitted to the **U.S. Food and Drug Administration** (FDA) an application relative to the BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) panel—a PCR test reporting in about 15 minutes "15 of the most common bacteria, viruses, and viral subtypes responsible for respiratory or sore throat infections."

SIEMENS Healthineers

SIEMENS HEALTHINEERS: Boosts Non-COVID-19 Revenue 8.3% for Fiscal Year 2023

Siemens Healthineers in Erlangen, Germany, shared results for its Q4 and full fiscal year 2023 as compared to Q4 2022 and 2022:

- Full year revenue was €21.6 billion (US$23.6 billion) compared to €21.7 billion (US$23.7 billion).
- Full year revenue, excluding rapid COVID-19 antigen tests, grew 8.3%.
- Full year diagnostics revenue fell to €4.5 billion (US$4.9 billion) from €6.0 billion (US$6.5 billion).
- Q4 revenue was up to €6.05 billion (US$6.6 billion) from €6.00 billion (US$6.5 billion).
- Q4 revenue, excluding COVID-19 antigen tests, was up 10.8%.
- Q4 diagnostics revenue fell to €1.2 billion (US$1.3 billion) from €1.4 billion (US$1.5 billion).
- Q4 diagnostics base revenue rose 1.6%.

In a presentation to analysts, CEO Bernd Montag, PhD, said a transformation program is "ongoing" and aimed at "right-size" of the company's structure. Siemens is seeking to cut €300 million (US$328 million) in costs by 2025. Among "compelling sub-segments" Montag called out are:

- Central lab "with Atellica (solution for immunoassay and clinical chemistry analysis) gaining full traction consolidating core lab footprint in one competitive offering."
- Specialty lab "with strong position."
- Point-of-Care "with accelerating top- and bottom-line growth."

QIAGEN

QIAGEN: Reports Q3 Growth of 6% in Non-COVID-19 Sales

Qiagen, headquartered in Venlo, Netherlands, reported Q3 financial results as compared to Q3 2022:

- Sales of $476 million were down 5% from $500 million.
- Instrument sales of $59 million were up 3% from $58 million.
- Molecular diagnostics sales of $254 million were down 1% from $257 million.
- Life sciences sales of $221 million fell 9% from $242 million.
- Base business sales rose 6% to $442 million from $417 million.
- COVID-19 sales plunged 59% to $34 million from $83 million.

Qiagen benefits from having more than 500,000 life sciences and molecular diagnostics customers and a "broad geographic presence," according to Thierry Bernard, CEO.

Roche

ROCHE: Reports Diagnostic Sales of $11.7B in Diagnostics in 9 Months, Launches New Assays

Roche Group in Basel, Switzerland, reported on nine months in 2023 as compared to the prior year period:

- Group sales fell to 44.1 billion Swiss francs (CHF) (US$49.8 billion) from 47 billion CHF (US$53 billion).
- Diagnostics division sales fell 25% to 10.4 billion CHF (US$11.7 billion) from 13.8 billion CHF (US$15.6 billion).
- COVID-19 product revenue of 0.4 billion CHF (US$452 million) plunged from 3.6 billion CHF (US$4 billion).
- Base business rose 9% and 7% for group sales and diagnostics, respectively.
- Core lab sales of 5.8 billion CHF (US$6.5 billion) were flat.
- Molecular lab revenue of 1.6 billion CHF (US$1.8 billion) plummeted 40% from 2.7 billion CHF (US$3 billion).
- Pathology lab sales of 1.0 billion CHF (US$1.1 billion) increased 7% from 975 million CHF (US$1.1 billion).

Matt Sause, Diagnostics CEO, told analysts that key 2023 launches included the IL-6 CE (claim extension) for neonatal sepsis, which runs on the cobas Elecsys analyzer. Early diagnosis of sepsis can prevent about 84% of neonatal deaths, he said.

DANAHER: Diagnostics Q3 Sales Fall but Cepheid Exceeds Expectations

Danaher Corporation, Washington, D.C., reported for its subsidiaries of **Beckman Coulter Diagnostics**, **Cepheid**, and **Leica Biosystems**. Here are Q3 results as compared to Q3 2022:

- Revenue fell 10.5% to $6.9 billion from $7.6 billion.
- Base business revenue was down 3%.
- Diagnostics sales decreased 16% to $2.2 billion from $2.6 billion.
- Life sciences revenue fell 1% to $1.70 billion from $1.72 billion.

During an earnings release call, Rainer Blair, CEO, said Beckman Coulter "had notable strength across clinical chemistry and immunoassay."

The Cepheid business division had a strong third quarter. Speaking about molecular diagnostics, Blair noted Cepheid's revenue in the quarter was about $350 million. This exceeded the expectation of $100 million. "The higher prevalence of COVID-19 drove both higher volumes and a preference for our four-in-one test," Blair said of the Xpert Xpress CoV-2/Flu/RSV plus.

BECTON, DICKINSON AND COMPANY: Base Revenue Up 5.1% in 2023

Becton, Dickinson and Company (BD) in Franklin Lakes, New Jersey, shared data for its Q4 and full fiscal year 2023, as compared to Q4 2022 and 2022:

- Full-year revenue grew 2.7% to $19.4 billion.
- Full-year revenue from base business, excluding COVID-19 testing revenue impact, was up 5.1%.
- Q4 revenue was up 6.8% to $5.1 billion.
- Q4 revenue from base business rose 7.3%.
- Full-year life sciences (including integrated diagnostics solutions and biosciences business units) revenue dropped 7.8% to $5.1 billion from $5.5 billion.
- Q4 life sciences revenue was up 1.8% to $606 million from $595 million.

During an earnings call, CEO Tom Polen said that BD launched 27 new products during 2023 that use artificial intelligence, robotics, and other technologies.

"Our robotic microbiology platform, BD Kiestra (total lab automation system), hit record sales this year, and we continue to drive strong double-digit growth in our BD COR (System) and BD MAX (Molecular Diagnostic System)," he said.

Polen noted BD's "relentless focus" on One-Stick Hospital Stay, which enables "needleless blood draws." TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

You may have thought that the long-running saga of the now-defunct **Theranos** had ended. But no, there is continuing litigation in the Grand Canyon State. A class action suit—*In re Arizona Theranos, Inc., Litigation, Case No. 2:16-cv-2138*—continues to move forward in the **U.S. District Court for the District of Arizona**. This class action suit has "reached settlements with defendant **Walgreens**, defendant Ramesh "Sunny" Balwani, and the entity that holds the remaining assets of the now-dissolved Theranos, Inc." Another statement filed with the court said "Walgreens and Balwani deny they did anything wrong."

MORE ON: *Theranos Class Action Lawsuit*

According to court documents, Walgreens agreed to pay $44 million into the settlement fund. One type of class member is described as "All purchasers of Theranos testing services, including consumers who paid out-of-pocket, through health insurance, or through any other source (collectively, 'purchasers') between November 2013 and June 2016." The next court date in this case is scheduled for February 6, 2024. It will be a hearing on final approval for terms of the settlement.

TRANSITIONS

• Cindy Jacke has joined **Labcorp** as its newest Senior Executive Director, Health Systems. Jacke previously held positions with **BioReference Laboratories**, **Pathline Emerge Pathology Services**, **Halfpenny Technologies**, and **Quest Diagnostics**.

• Don Hardison was named Chairman of the board for St. Louis-based **Geneoscopy**, a company developing molecular diagnostic tests for gastrointestinal health. Hardison previously held executive positions with **Good Start Genetics**, **Exact Sciences**, **Labcorp**, **Quest Diagnostics**, and **SmithKline Beecham Clinical Laboratories**.

CORRECTION: In the Oct. 23, 2023, issue of THE DARK REPORT, in the sidebar on pg. 9 titled, "Accreditors' Standards Cited for Proficiency Testing," a printer error showed standards PT 9, PT 15, and PT 10 as CAP, when in fact they are COLA standards. Also, the CAP standards were missing their corresponding titles, shown correctly below:

- **COM.01400 (All Common Checklist, PT Attestation Statement).** The proficiency testing/external quality assessment attestation statement is signed by the lab director or designee and all individuals involved in the testing process.
- **COM.01700 (All Common Checklist, PT and Alternative Assessment Result Evaluation).** Ongoing evaluation of proficiency testing/external quality assessment and alternative assessment results with appropriate corrective action are taken for each unacceptable result.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, December 26, 2023.

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UPCOMING...

- ***THE DARK REPORT'S 'Top Ten Lab Industry Stories' for 2023 identify most influential events of the year.***
- ***Update on adoption and use by clinical labs and pathology groups of Lean, Six Sigma, ISO 15189.***
- ***In a tight market for skilled lab professionals, how one innovative lab is attracting and retaining staff.***

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